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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,064	02/13/2006	Akira Shimotoyodome	282148US0PCT	7467

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EXAMINER	
SZNAIDMAN, MARCOS L	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
06/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/568,064	SHIMOTOYODOME ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-15* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 page / 04/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's reply filed on April 2, 2010.

Status of Claims

Amendment of claim 5 is acknowledged.

Claims 1-5 and 7-15 are currently pending and are the subject of this office action.

Claims 1-4 and 7-9 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 4, 2008.

Claims 5 and 10-15 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/13652 filed on 09/17/2004, and claims priority to foreign application: JAPAN 2003-326140 filed on 09/18/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Rejection not Necessitated by Amendment)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 5, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iawo et. al. (JAPAN 2003-095942, 03/24/2003, machine translated, cited in prior office action).

Claim 5 recites a method for improving endurance, which comprises administering to a subject in need thereof an effective dose of a composition comprising catechins, wherein said subject in need thereof is a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise.

Claim 10 further limits claim 5, wherein the catechin is selected from the group consisting of: gallocatechin, epigallocatechin, gallocatechingallate and epigallocatechingallate.

Claim 14 further limits claim 10, wherein the catechin is: epigallocatechingallate.

For claims 5, 10 and 14, Iawo et. al. teach a method to reinforce and increase activation of the muscular system, improvement in athletic ability (improving endurance), fatigue mitigation (ameliorating fatigue) and improve physical condition by administering ca catechin (see paragraphs [0011]-[0013]). By catechin the authors

encompass: epicatechingallate, epigallocatechingallate, catechingallate (see paragraph [0018]).

Iawo does not teach the administration of a catechin to a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise. However, since Iawo teaches that catechins reinforce and increase activation of the muscular system, improvement in athletic ability (improving endurance), fatigue mitigation (ameliorating fatigue) and improve physical condition, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to administer catechins to any person in need of such improvements, like for example subject that regularly exercise, are involved in sports or any other activity, including walking, that requires repeated muscle exercise, thus resulting in the practice of claims 5, 10 and 14 with a reasonable expectation of success.

2) Claims 11-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iawo et. al. (JAPAN 2003-095942, 03/24/2003, machine translated, cited in prior office action) as applied to claims 5, 10 and 14 further in view of Demeule et. al. (Current Medicinal Chemistry (2002) 2:441-463, cited in prior office action).

Claim 11 further limits claim 10, wherein the catechin is at least gallocatechin.

Claim 12 further limits claim 10, wherein the catechin is at least epigallocatechin.

Claim 13 further limits claim 10, wherein the catechin is at least gallocatechingallate.

Claim 15 further limits claim 5, wherein said catechin is at least: gallocatechin and epigallocatechin.

Iawo teaches all the limitations of claims 11-13 and 15 except for the catechins gallocatechin, epigallocatechin and gallocatechingallate. However, Demeule teaches that gallocatechin, epigallocatechin and gallocatechingallate are catechins like epigallocatechingallate, epicatechingallate, epicatechin and epigallocatechin that are found in tea leaves (see page 443 Figure 1) and that they all share common structural and biological properties (see entire document).

Since Iawo teaches a method of improving endurance with the catechins: epicatechingallate, epigallocatechingallate, catechingallate , and since Demeule teaches that gallocatechin, epigallocatechin and gallocatechingallate are catechins, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (any catechin) for another (gallocatechin, epigallocatechin and gallocatechingallate) with an expectation of success, since the prior art establishes that both function in similar manner, thus resulting in the practice of claims 11-13 and 15, with a reasonable expectation of success.

Double Patenting (New Rejection not Necessitated by Amendment)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5 and 10-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7 and 13 of copending Application No. 12/307,342. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite methods for improving exercise effects comprising administering an effective amount of catechins to a subject in need thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5 and 10-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 10-12 and 26 of copending Application No. 11/626,032. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both applications recite methods for improving exercise effects comprising administering an effective amount of catechins to a subject in need thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5 and 10-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 7-12 of copending Application No. 11/045,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite methods for improving exercise effects or enhancing physical activities comprising administering an effective amount of catechins to a subject in need thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, first paragraph (written description).

Due to Applicant's amendment of claim 5, the 112, first paragraph (written description) rejection is now moot.

Rejection under 35 USC 112, first paragraph (written description) is withdrawn.

Claims rejected under 35 USC 102(e)

Applicant's arguments have been fully considered and are persuasive. The Lines prior art (US 2004/0126461) used as a reference in the previous office action does not qualify as prior art since it first disclosed the method of the instant application in the non-provisional application 10/692,178 dated 10/23/2003 and as such it does not qualify as 102(e) prior art, since the instant application claims priority date of 09/18/2003.

Rejection under 35 USC 102(e) is withdrawn.

Claims rejected under 35 USC 103 (a)

For the same reasons discussed for the 102(e) rejection above, the 103(a) rejection is now moot.

Rejection under 35 USC 103(a) is withdrawn.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
May 24, 2010.